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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,848	03/29/2006	Tai-Wha Chung	1877-1001	2217

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,848	CHUNG ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/08 & 3/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The rejection of claims 6 and 8 as being anticipated by Toyama et al (EP 0 199 196) is withdrawn in view of the amendment to the claims.

2. The rejection of claims 6 and 8 as being anticipated by Fraeyman et al (Hybridoma. 1987. Vol. 6, No. 6, pp. 565-574) is withdrawn in view of the amendment to the claims.

3. The rejection of claims 6 and 8 as being anticipated by Song et al (clinical Chemistry. Vol. 47, No. 6, Supplement, 2001. A152) is withdrawn in view of the amendment to the claims.

4. The rejection of claims 6-8 under 35 USC 102(f) is withdrawn in view of the 37 CFR 131 declaration

5. The rejection of claim 7 under the deposit rule is withdrawn in view of the 37 CFR 132 declaration.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the detection of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis using mAb KCTC 10261 to

detect AsAGP, does not reasonably provide enablement for the diagnosis of any and all liver diseases using any other monoclonal antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 6-8 are directed to a method for diagnosing a liver disease comprising the detection of asialo alpha-1-acid glycoprotein (AsAGP) in blood or serum using a monoclonal antibody, and specifically KCTC 10261 BP.

The specification discloses the detection of AsAGP in blood samples from sources including normal, non-hepatic disease, acute hepatitis, chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis, using KCTC 10261; however, it is unclear from the results and discussion therein how it was determined that "a liver disease" can be diagnosed using the data presented. The specification states that the cutoff value for diagnosing a liver disease is 1.50 ug/ml when mAb KCTC 10261 is used. Normal and non-hepatic samples have an average of 1.00 ug/ml, and in patient groups suffering from acute hepatitis, chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis, the blood level of AsAGP averaged 1.33 ug/ml, 1.63 ug/ml, 3.12 ug/ml and 3.64 ug/ml. The specification also states that about 10% of the control samples have AsAGP value over 1.50 ug/ml.

It would appear from this data that the specification is only enabled for the detection of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis using mAb KCTC 10261 and only when the detected level of AsAGP is above 1.50 ug/ml. The specification is not enabled for the diagnosis of any and all liver diseases using any monoclonal antibody except for MAb KCTC 10261.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the claim is incomplete. There is no correlation between the measured amount of AsAGP in a test sample and the diagnosis of a liver disease. Specifically, claim 6 lacks method steps such as contacting the monoclonal antibody with a sample suspected of containing AsAGP; measuring the amount of the complexes form between the antibody and as AsAGP in the sample and relating the measured amount of AsAGP in the same with a liver disease, etc.

Claim 6 is currently written in the narrative form and the method steps are not clearly delineated thus making the meets and bounds of the claim difficult to ascertain.

Response to Arguments

10. Applicant's arguments filed 28 March 2008 have been fully considered but they are not persuasive.

Applicant asserts that the amendment to claim 6 obviates the enablement rejection. However, claim 6 stills recite a method for diagnosing any and all liver disease and is not limited to only those disclosed in the specification. Specifically, chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the

advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
June 30, 2008